Response to the European Commission consultation on draft detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use ('CT-3')

September 2010

The National Health Service (NHS) is one of the largest publicly funded healthcare systems in the world, providing the majority of healthcare in England. The NHS is committed to the principle of universal access to healthcare which is free at the point of use. Every 36 hours the NHS sees over 1 million patients who make use of a wide range of health services including primary care, in-patient care, long-term healthcare, ophthalmology and dentistry. The NHS is also the largest employer in Europe with more than 1.5 million people on its payroll.

The English NHS is represented in Europe by the NHS European Office. The Office was launched in September 2007 and its role is to inform the NHS of EU affairs and to ensure that the NHS contributes positively to EU developments.

The NHS has a strong history in clinical trials and, through its structure and access to patients and patient databases, can play a vital role in the development and uptake of innovative new medicines and technologies. Furthermore, clinical trials in the UK have made a large contribution to improved healthcare delivery around the globe and there continues to be enormous research potential in the NHS with academic and research partners.

In recent years however, the UK has lost ground internationally as a leading clinical trials environment. A 2009 UK government report showed that the UK's involvement in global clinical trials dropped dramatically from 6% in 2002 to 2% in 2006, while the percentage of EU products in clinical trial development in the UK fell from 46% in 2002, to 24% in 2007. Therefore, there is an urgent need to improve the climate for clinical trials in the UK. It is our view that a review of the existing Clinical Trials Directive 2001/20/EC can help to achieve this.

Thus, we strongly advocate the need for a full revision of the Directive. In the meantime, we welcome the Commission's attempt to deliver clarification on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use. The new text is clear and informative.

In January 2010 we responded to the European Commission public consultation on the functioning of the Clinical Trials Directive (CTD). In this response, we explained that the reporting of suspected unexpected serious adverse reactions (SUSARs) has increased since implementation of the current CTD, and this is a disincentive to engage in clinical trials. We hope that clarifying the procedures and modalities of reporting SUSARs to the Community database will restrict the scope for variations in interpretation of the law and could improve the current situation.

We also noted concerns raised by NHS organisations about the identification of SUSARs and the definition of what adverse events may be expected during a given clinical trial. Many investigators do not realise the importance of such information in ensuring that SUSARs are truly unexpected events rather than those which may reasonably occur, especially in trials where individuals are not in good health when enrolled.

Therefore, whilst we appreciate the Commission's attempts to improve guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use, we continue to advocate a full revision of Directive 2001/20/EC.

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